

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

) THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.)) CIVIL ACTION NO. 99-20593
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9012

Bartle, J.

February 18, 2013

Glenda S. Macy ("Ms. Macy" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2003, claimant submitted Part II of a Green Form to the Trust signed by her attesting physician, Antoine M. Adem, M.D., in which she sought Matrix A-1, Level II benefits.³ Based on an echocardiogram dated June 18, 2002, Dr. Adem attested that claimant had severe mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left atrial dimension, and a reduced

2. (...continued)

serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who has factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Ms. Macy also submitted a second Part II of a Green Form signed by Dr. Adem in which she sought Matrix A-1, Level III benefits. This Part II is not relevant to disposition of this claim.

ejection fraction in the range of 50% to 60%.⁴ Dr. Adem also attested that claimant did not have chordae tendinae rupture.⁵ Based on these findings, claimant would be entitled to Matrix A-1, Level II⁶ benefits in the amount of \$340,223.⁷

In February, 2004, the Trust forwarded the claim for review by Ernest C. Madu, M.D., F.A.C.C., F.E.S.C., one of its auditing cardiologists. In audit, Dr. Madu concluded that there was a reasonable medical basis for Dr. Adem's findings that claimant had severe mitral regurgitation, an abnormal left atrial dimension, and pulmonary hypertension secondary to moderate or

4. Dr. Adem also attested that claimant had surgery to repair or replace her mitral valve after use of Pondimin® and/or Redux™ and New York Heart Association Functional Class III symptoms. These conditions are not at issue in this claim.

5. The Settlement Agreement provides that a claim will be reduced to the B-1 Matrix if a claimant pursuing a claim for Matrix Benefits for damage to the mitral valve has chordae tendinae rupture. See Settlement § IV.B.2.d.(2)(c)(ii)(c).

6. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60% are each one of the complicating factors needed to qualify for a Level II claim.

7. Ms. Macy previously was paid Matrix B-1, Level III benefits in the amount of \$136,664. According to the Trust, if entitled to Matrix A-1, Level II benefits, claimant would be entitled to Matrix Benefits in the amount of \$476,887. The amount at issue, therefore, is the difference between the Matrix B-1, Level III benefits already paid and the amount of Matrix A-1, Level II benefits.

greater mitral regurgitation. Dr. Madu also determined that Ms. Macy did not suffer from chordae tendinae rupture.

By letter dated March 30, 2004, the Trust advised Ms. Macy that her claim was potentially payable on Matrix A and requested additional medical records pursuant to Court Approved Procedure ("CAP") No. 4, as adopted in Pretrial Order ("PTO") No. 2805 (Mar. 26, 2003). Following a review of claimant's additional medical records, Dr. Madu issued an amended Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue. In particular, Dr. Madu determined that there was no reasonable medical basis for Dr. Adem's findings that claimant did not have chordae tendinae rupture. Dr. Madu explained, "The operative report submitted by claimant clearly indicates the presence of 'ruptured chordae tendinae to the anterior valve leaflet.'"

Based on Dr. Madu's amended finding that claimant had chordae tendinae rupture, the Trust issued a post-audit determination that Ms. Macy was entitled only to Matrix B-1, Level II benefits.⁸ Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested

8. As the Trust does not contest Ms. Macy's entitlement to Level II benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1. If Ms. Macy's claim for Level II benefits is payable only on Matrix B-1, Ms. Macy will not receive any additional payment because the amount to which she would be entitled for her Matrix B-1, Level II claim is less than the amount she already received for her Matrix B-1, Level III claim. See Settlement Agreement § IV.C.3.

this adverse determination.⁹ In contest, claimant argued that she should prevail because she did not have chordae tendinae rupture at the time she first qualified for Level II benefits. In support, claimant relies on echocardiograms dated August 28, 1998, June 18, 2002 (the echocardiogram of attestation), and October 7, 2002. She also submitted affidavits of Randall G. Johnson, M.D., and Gary S. Benton, M.D. In his affidavit, Dr. Johnson stated that he received claimant's October 7, 2002 transesophageal echocardiogram and "saw no evidence of ruptured mitral valve chordae tendinae." According to claimant, a transeophageal echocardiogram provides a better view of the mitral valve than a transthoracic echocardiogram. In the second affidavit, Dr. Benton, the surgeon who performed Ms. Macy's mitral valve replacement surgery, stated that he noticed claimant had ruptured chordae tendinae but opined, without any explanation, that the rupture occurred subsequent to Ms. Macy's June 19, 2002 coronary artery bypass surgery.

The Trust then issued a final post-audit determination, again denying Ms. Macy's claim for Matrix A-1, Level II Benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the

9. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Macy's claim.

Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Macy's claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5239 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 10, 2005, and claimant submitted a sur-reply on December 2, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor¹⁰ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that Ms. Macy did not have chordae tendinae rupture. See id. at Rule 24. Ultimately, if we determine that there was no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. at Rule 38(a). If, on the other hand, we determine that there was a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. at Rule 38(b).

In support of her claim, claimant argues that "[t]he issue presented is whether a claim that meets every criterion for payment on the A Matrix is invalidated by the subsequent development of a reduction factor." Ms. Macy asserts that her chordae tendinae rupture did not develop until after the date of the echocardiogram that forms the basis of her claim for Matrix A-1, Level II Benefits - June 18, 2002. Ms. Macy contends that "it defeats the purpose of the reduction factors to apply them retroactively insofar as the regurgitation previously came to existence without the contribution of a reduction factor."¹¹

11. Claimant concedes that the condition of chordae tendinae rupture was present by the time of her mitral valve replacement surgery.

In response, the Trust argues that Dr. Madu properly based his finding of chordae tendinae rupture on his review of claimant's operative report and the echocardiogram of attestation. The Trust also contends that, under the Settlement Agreement, the presence of chordae tendinae rupture reduces a mitral valve claim to the B-1 Matrix, regardless of whether the chordae tendinae rupture is present on the echocardiogram of attestation.

The Technical Advisor, Dr. Abramson, reviewed claimant's June 18, 2002 echocardiogram and concluded that there was no reasonable medical basis for Dr. Adem's finding that claimant did not have chordae tendinae rupture. In particular, Dr. Abramson explained:

Based on my review of the Special Master Record, including the two Green Forms, seven echo reports, affidavits from two other physicians, the report of the Auditing Cardiologist, the operative report, the transthoracic echocardiogram from 6/18/02, and the transeophageal echocardiogram from 10/7/02, there are ruptured chordae tendinae on the echocardiogram of 6/18/02 and there is no reasonable medical basis for the physician completing the diet-drug recipient's claim form to state that Glenda Macy did not have a chordae tendinae rupture.

....

I reviewed the TTE from 6/18/02 and the TEE from 10/07/02.... In two views, short axis of the LV (-1:23:30-1:23:20) and a zoomed in apical-4-chamber (-1:12:10-1:11:50), there are hypermobile linear echodensities in the area of the subvalvular mitral apparatus which generally represent ruptured chordae tendinae. It is unlikely that these hypermobile structures represent redundant

chordae since the surgeon clearly saw the ruptured chordae when he inspected the mitral valve during the 3/06/03 surgery. The TEE also demonstrates oscillating structures attached to the anterior mitral leaflet (00:00:21-00:00:26) which also represent ruptured chordae. Signs of hypertrophic obstructive cardiomyopathy including LVH with basal septal thickening, LVOT gradient and moderate [mitral regurgitation] are also present on the TEE.

To summarize this Claimant's complicated cardiac issues, she has hypertrophic obstructive cardiomyopathy with at least moderate [mitral regurgitation] which was noted on her TTE from 7/18/98 and mentioned in subsequent echocardiograms (except the TEE from 10/07/02-which did not mention LVH, but it was present upon my review) including the study from 2/26/03. This is a disease process (also known as IHSS) which usually causes mitral regurgitation. In the 6/18/02 echo, she was reported as having moderate to severe [mitral regurgitation], which is the same [mitral regurgitation] severity as the 2/26/03 echo. If the ruptured chordae occurred during the time interval between the two echocardiograms, the severity of the [mitral regurgitation] should have worsened, which it did not. This disease process (IHSS) is also associated with ruptured chordae tendinae, "Chordal rupture may ... be secondary to rheumatic heart disease, bacterial endocarditis, mitral valve prolapse, connective tissue disorders, myocardial infarction, idiopathic hypertrophic subaortic stenosis (IHSS) and trauma" (Weyman, 2nd ed, p. 458). The hypermobile structures seen in the LV in both the 6/18/02 and 10/07/02 echocardiograms represent ruptured chordae tendinae as described in the operative report from 3/06/03. These were not noticed during the surgery on 6/19/02, because you do not open up the ventricle during coronary artery bypass surgery as you do for mitral valve surgery.

In summary, (1) chordae tendinae rupture can be determined from the Claimant's

echocardiogram of 6/18/02. (2) The Claimant did have a chordae tendinae rupture when her echocardiogram was taken on 6/18/02.

(3) There is no reasonable medical basis for the Attesting Physician to state that the chordae tendinae rupture is not evident on the 6/18/02 echocardiogram.

After reviewing the entire show cause record, we find claimant's arguments to be without merit. Although claimant submitted the affidavits of Dr. Johnson and Dr. Benton, neither physician stated that he had reviewed claimant's June 18, 2002 echocardiogram and determined that it did not demonstrate chordae tendinae rupture. Dr. Abramson, on the other hand, reviewed claimant's June 18, 2002 echocardiogram and specifically determined that there was evidence of chordae tendinae rupture. Dr. Abramson also determined that Dr. Johnson's and Dr. Benton's opinions that Ms. Macy's chordae tendinae rupture occurred after June 18, 2002 were unsupported. As explained by Dr. Abramson, if Ms. Macy's chordae tendinae ruptured between her June 18, 2002 and February 26, 2003 echocardiograms the severity of her mitral regurgitation would have worsened, but it did not.¹²

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she did not have chordae tendinae rupture. Therefore, we will affirm the Trust's denial of Ms. Macy's claim for Matrix A-1, Level II benefits.

12. Despite an opportunity to do so, claimant did not respond to the Technical Advisor Report. See Audit Rule 34.